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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,087	10/15/2001	Martin F. Yanofsky	19452A-000940US	9499

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER
MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
1638	10

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/981,087	YANOFSKY ET AL.	
	Examiner	Art Unit	
	Ashwin Mehta	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40 and 65-78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40 and 65-78* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 October 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Drawings

1. The brief description to Figure 2 on page 9 indicates that this figure has parts A-D. However, these parts are not labeled on the figure. The figure should be amended be inserting these labels.

Similarly, the brief description to Figure 5 indicates that this figure has parts A and B. However, the parts are not labeled on the figure. The brief description of Figure 5B on page 10 also indicates that parts within it are labeled (a)-(f), which also do not appear in the figure. The figure should be amended by inserting these labels.

Figure 8 shows the nucleotide sequences and corresponding amino acid sequences of Arabidopsis AGL1 and AGL5. However, it is not clear from the figure, which sequences are AGL1 and which are AGL5. The figure should be amended to more clearly identify the AGL1 sequences from the AGL5 sequences.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings

should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

Applicant is required to submit a proposed drawing correction in reply to this Office action. However, formal correction of the noted defect may be deferred until after the examiner has considered the proposed drawing correction. Failure to timely submit the proposed drawing correction will result in the **ABANDONMENT** of the application.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 40 and 65-78 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 41-58 of copending Application No. 09/708,584 ('584). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '584 and the instant invention both involve suppressing the expression of an AGL8-like gene product. The claims of '584 encompass transgenic seed plants that produce seed of decreased size, wherein the plant comprises an exogenous nucleic acid encoding a protein having greater than 50% amino acid identity to SEQ ID NO: 2, and a method for producing plants that produce seeds of decreased size, comprising introducing into the plant an exogenous nucleic acid molecule encoding a protein having at least 70% amino acid identity with SEQ ID NO: 2. The amino acid sequence set forth in SEQ ID NO: 2 of the instant application and '584 are identical. The instantly claimed plants, and the plants produced by the instantly claimed methods have enhanced lignification, but also involve suppressing SEQ ID NO: 2 (AGL8) expression. As expression of the same gene product is suppressed, it is obvious that the plants of the invention of '584 and the plants of the instant claims and plants produced by the instantly claimed methods display both enhanced lignification and produce seed of decreased size.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 40, 65, and 67-78 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn towards a method of enhancing lignification in a vascular plant, comprising suppressing expression of an AGL8-like gene product comprising a polypeptide at least 50% identical to SEQ ID NO: 2; or said method comprising introducing into the plant a promoter operatively linked to a polynucleotide in sense orientation, the polynucleotide encoding a polypeptide at least 50% identical to SEQ ID NO: 2, thereby suppressing expression of the AGL8-like gene product; or said method comprising introducing into the plant a promoter operatively linked to a polynucleotide in antisense orientation, the polynucleotide encoding a polypeptide at least 50% identical to SEQ ID NO: 2, thereby suppressing expression of the AGL8-like gene product; or said method wherein said plant is a woody plant, or a leguminous plant, or a forage grass; any transgenic plant characterized by enhanced lignification, the transgenic plant comprising a promoter operatively linked to a polynucleotide in sense or antisense orientation, the polynucleotide encoding a polypeptide at least 50% identical to SEQ ID NO: 2; any tissue derived from said transgenic plant.

The specification indicates that AGL8 RNA accumulates during inflorescence development in the inflorescence stem and cauline leaves, and in later stages of flower development. AGL8 is detected in the inflorescence meristem upon switching from vegetative to

reproductive development. AGL8 accumulates in the inflorescence meristem and the stem as the inflorescence stem elongates (page 21, line 6 to page 22, line 2). The specification also indicates that a mutation designated "ful-1" was identified using large scale insertional mutagenesis with enhancer and gene trap Ds transposable elements. AGL8 mRNA was not detected in flowers of the mutant plants. Fruit of the agl8 mutant displayed additional ectopic lignification of the internal valve mesophyll layer (page 68, line, line 25 to page 69, line 8).

However, the only AGL8-related gene product described by the specification is that set forth in SEQ ID NO: 2. The specification indicates on page 26, lines 14 a tomato AGL8 ortholog is available as EST244966 under accession number AI486645. However, this is not a complete sequence. Further, the entry for this tomato EST does not mention anything about AGL8. The specification also indicates that an AGL8 ortholog from Sinapis alba, termed SaMADS B, is described in Menzel et al. (page 26, lines 14-17) (Plant J., 1996, Vol. 9, lines 399-408). However, Menzel et al. do not mention AGL8 at all, but rather compare SaMADS B with other MADS box genes (page 400, second column, second paragraph; Figure 2b). The specification also indicates that AGL8 has amino acid sequences that make up a highly conserved MADS domain, a weakly conserved "I" domain, a moderately conserved "K" domain, and a variable "C" domain (page 19, line 30 to page 21, line 5). However, the specification also indicates that AGAMOUS and other genes encode proteins with these domains (page 20, lines 3-16). The presence of a MADS box alone then cannot be correlated specifically with AGL8 function. The specification then does not provide an adequate description of the sequences encoding all AGL8-related gene products that can be manipulated in the claimed plants and methods. See Fiers vs. Sugarno, 25 USPQ 2d (CAFC 1993) at 1606, which states that "[a]n

adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself". Given the breadth of the claims encompassing any AGL8-related gene product that has at least 50% identity with SEQ ID NO: 2, and the lack of guidance of the specification as discussed above, the specification fails to provide an adequate written description of the multitude of nucleotide sequences encompassed by the claims.

4. Claims 40 and 65-74 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of enhancing lignification in a vascular plant, comprising an Arabidopsis plant comprising a Ds transposable element in the AGL8 gene, or comprising introducing into a vascular plant a polynucleotide encoding SEQ ID NO: 2 in sense or antisense orientation, such that expression of the AGL8-like gene product is suppressed, does not reasonably provide enablement for any other method for suppressing the expression of an AGL8-like gene product, or polynucleotides encoding AGL8-like polypeptides having at least 50% identity with SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or the invention commensurate in scope with these claims.

The claims are broadly drawn towards a method of enhancing lignification in a vascular plant, comprising suppressing expression of an AGL8-like gene product comprising a polypeptide at least 50% identical to SEQ ID NO: 2; or said method comprising introducing into the plant a promoter operatively linked to a polynucleotide in sense orientation, the polynucleotide encoding a polypeptide at least 50% identical to SEQ ID NO: 2, thereby

suppressing expression of the AGL8-like gene product; or said method comprising introducing into the plant a promoter operatively linked to a polynucleotide in antisense orientation, the polynucleotide encoding a polypeptide at least 50% identical to SEQ ID NO: 2, thereby suppressing expression of the AGL8-like gene product; or said method wherein said plant is a woody plant, or a leguminous plant, or a forage grass; any transgenic plant characterized by enhanced lignification, the transgenic plant comprising a promoter operatively linked to a polynucleotide in sense or antisense orientation, the polynucleotide encoding a polypeptide at least 50% identical to SEQ ID NO: 2; any tissue derived from said transgenic plant.

The specification indicates that AGL8 RNA accumulates during inflorescence development in the inflorescence stem and cauline leaves, and in later stages of flower development. AGL8 is detected in the inflorescence meristem upon switching from vegetative to reproductive development. AGL8 accumulates in the inflorescence meristem and the stem as the inflorescence stem elongates (page 21, line 6 to page 22, line 2). The specification also indicates that a mutation designated "ful-1" was identified using large scale insertional mutagenesis with enhancer and gene trap Ds transposable elements. AGL8 mRNA was not detected in flowers of the mutant plants. Fruit of the agl8 mutant displayed additional ectopic lignification of the internal valve mesophyll layer (page 68, line, line 25 to page 69, line 8).

However, neither the specification nor the prior art teaches any AGL8-related gene other than that of Arabidopsis (instant SEQ ID NO: 1). The specification indicates that that the Sinapis alba SaMADS B gene encodes an AGL8 ortholog and is taught in Menzel et al. (Plant J., 1996, Vol. 9, lines 399-408; specification, pages 16, lines 30-34), and that a tomato AGL8 ortholog is available under accession number AI486645 (page 26). However, Menzel et al. do

not mention AGL8 at all, but rather compare SaMADS B with other MADS box genes (page 400, second column, second paragraph; Figure 2b). The tomato sequence under accession number AI486645 is not a complete protein, and nothing is mentioned in the entry teaching that it is an AGL8-like gene product. Given the teachings of Menzel et al. and the entry of the accession number one would not conclude that SaMADS B or the tomato EST are AGL8-related genes. The specification also mentions that an AGL8-like gene can be an AGL8 ortholog, such as a Eucalyptus ortholog (page 26, lines 12-4). However, the nucleotide sequences of this and other AGL8-like gene products are not taught. See In re Bell, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and In re Deuel, 34 UPSQ2d, 1210 (Fed. Cir. 1995), which teach that the mere existence of a protein does not enable claims drawn to a nucleic acid encoding that protein. See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

The specification does not teach mutant plants of other species that comprised Ds transposable element insertions in any AGL8-related gene, other than for Arabidopsis. The specification cites Sundaresan et al. (Genes Dev., 1995, vol. 8, pages 1797-1810) as describing the mutagenesis conducted to produce the AGL8 mutant plant. Sundaresan et al. teach a transposon system for generating gene trap and enhance trap insertions in plants. Sundaresan et al. did not set out to specifically mutate the AGL8 gene. The instant specification indicates that sequence analysis indicated that a Ds element in one of the plants of Sundaresan et al. had inserted into the untranslated leader of AGL8 (page 68, lines 1-26). However, as the sequences of AGL8 genes in other plant species are not known, one cannot determine if AGL8-like gene

has been disrupted. In the absence of such guidance, undue experimentation would be required for one skilled in the art to identify a vascular plant in which an AGL8-like gene is disrupted by insertional mutagenesis.

Further, the specification does not teach any other method, except by co-suppression or expression of the antisense sequence, using nucleotide sequences that encode SEQ ID NO: 2, to suppress expression of an AGL8-like gene. The specification does not teach how the expression of AGL8-like genes or gene products are controlled in plants, and nor does it teach how AGL8-like gene products are regulated. In the absence of further guidance, it would require undue experimentation by one skilled in the art to determine the regulators of AGL8-like genes or gene products, and to determine other methods in which such regulators can be exploited to suppress expression of AGL8-like gene products. See Genentech, Inc. V. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention. Given the breadth of the claims encompassing any method of suppressing AGL8-related gene products in any vascular plant, or in which the suppression is by antisense or cosuppression techniques that involve the use of sequences other than those encoding SEQ ID NO: 2, or the identification of mutations in AGL8-like genes of plants other than Arabidopsis, unpredictability of the prior art and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 40, 65, and 66 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mandel et al. (Nature, 1995, Vol. 377, pages 522-524).

The claims are broadly drawn towards a method of enhancing lignification in a vascular plant, comprising suppressing expression of an AGL8-like gene product comprising a polypeptide at least 50% or 75% identical to SEQ ID NO: 2, or wherein the AGL8-like gene product comprises SEQ ID NO: 2.

Mandel et al. (Nature) teach the production of transgenic Arabidopsis plants transformed with the APETALA1 (AP1) gene, and tissues from the transgenic plant (pages 522-523). AP1 is a negative regulator of AGL8, as evidenced by Mandel et al. (Plant Cell, 1995, Vol. 7, pages 1763-1771, see abstract). In light of this evidence, it is inherent that method of transgenically expressing AP1 of Mandel et al. (Nature) also suppresed the expression of AGL8. The Examiner is unable to determine whether the plant produced by the method taught by Mandel et al. (Nature) possesses the unrecited property of having enhanced lignification. The Examiner does not have sufficient facts to determine whether the method taught by Mandel et al. (Nature) will also produce plants that have enhanced lignification. The Examiner cannot conclude that the subject mater of the claim would have been obvious since it cannot determine whether the

method causes enhanced lignification. The Examiner is not in a position to make either a conclusion of "inherency/anticipation" or "obviousness" since the record does not allow one to determine if and how the claimed subject matter differs from the prior art. Accordingly, the burden shifts to Applicants to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention. See *In re Best* 195 USPQ 430, 433 (CCPA 1977).

6. No claim is allowed.

Contact Information

Any inquiry concerning this communication from the examiner should be directed to Ashwin Mehta whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

ASHWIN D. MEHTA, PH.D
PATENT EXAMINER

February 10, 2003